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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,136	03/16/2001	Beverly B. Teter	UMARY3	7554

7590 07/02/2007
Peter J. Batch III, Esq.
Synnestvedt Lechner & Woodbridge LLP
P.O. Box 592
Princeton, NJ 08542-0592

EXAMINER

OGUNBIYI, OLUWATOSIN A

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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07/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/720,136	TETER, BEVERLY B.	
	Examiner	Art Unit	
	Oluwatosin Ogunbiyi	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18, 25, 26, 38, 45 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-18, 25, 26, 38, 45 and 51 is/are rejected.
- 7) ☒ Claim(s) 14, 25, 26 and 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

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The examiner in charge of the application has changed. This application is now in Art Unit 1645 and the examiner is Oluwatosin Ogunbiyi

RESPONSE TO AMENDMENT

The amendment filed 5/12/06 has been entered into the record. Claims 11,14,25, and 51 have been amended. Claims 10-18,25,26,45 and 51 are pending and are under examination.

Rejections Withdrawn

In view of applicant's amendment to claims 14 and 51, the rejection over claims 14 and 51 under 35 U.S.C. 112 second paragraph on pg. 2 of the previous office action is withdrawn.

Rejection of claims 10-12, 18, 38 and 45 under 35 U.S.C 103(a) as being unpatentable over Ohzeki et al (4,569,846) in view of Isaacs et al (US 5,434,182) is withdrawn in favor of new grounds of rejection set forth below.

Rejection of claims 15-17,25 and 26 under 35 U.S.C 103(a) as being unpatentable over Windholz et al., The Merck Index 10th edition, 1983, p. 893 abstract no. 6100 in view of Isaacs et al (US 5,434,182) is withdrawn in favor of new grounds of rejection set forth below.

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New Objection/Rejections

Claim Objections

Claims 14,25,26 and 51 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The claims are drawn to an animal feed composition according to claim 10, further comprising at least one antibiotic, wherein the amount of antibiotic in the animal feed comprises less than 50% of an optimal antibiotic supplement.

Claim 10 is drawn to "in an animal feed composition comprising crude protein and an antibiotic supplement, the improvement comprising replacing all or a portion of said antibiotic supplement with an anti-bacterial amount of an anti-bacterial fatty acid component, wherein the anti-bacterial fatty acid component is a high lauric acid natural oil or a derivative thereof having a high lauric acid content.

The *recitation of further comprising at least one antibiotic* in Claim 14 broadens claim 10 because claim 10 replaces all of an antibiotic supplement by reciting *in an animal feed composition comprising crude protein and an antibiotic supplement, the improvement comprising replacing all said antibiotic supplement*.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14,25,26 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.*

The claims are drawn to an animal feed composition according to claim 10, further comprising at least one antibiotic, wherein the amount of antibiotic in the animal feed comprises less than 50% of an optimal antibiotic supplement.

Claim 10 is drawn "in an animal feed composition comprising crude protein and an antibiotic supplement, the improvement comprising replacing all or a portion of said antibiotic supplement with an anti-bacterial amount of an anti-bacterial fatty acid component, wherein the anti-bacterial fatty acid component is a high lauric acid natural oil, or a derivative thereof having a high lauric acid content".

The specification does not contemplate an animal feed composition as set forth in claim 10 wherein a portion of said antibiotic supplement has been replaced wherein said animal feed composition further comprises at least one antibiotic.

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The instant claim now recites limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention and that the invention, in that context, is whatever is now claimed. See MPEP 2163.02. Also, the failure to meet the written description requirement under 35 USC 112, first paragraph arises when the claims are changed after the filing date to change the scope of the disclosure (see MPEP 2163.05).

Applicants pointing to the specification by page line and number where specific written description support for the new claimed invention can be found bests resolve this issue.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13,14,25,26 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 13, the metes and bounds of "essentially free of antibiotic supplements" is not clear. It is not clear how the term limits replacing a portion of or all of the antibiotic supplement in the animal feed composition as recited in claim 10. For instance, if a portion of antibiotic supplement is replaced does this mean the composition is essentially free? What are the metes and bounds of essentially free? Clarification is required as to the term essentially free in the claim as it relates to claim 10.

As to claims 14, 25,26 and 51 the recitation of "further comprising at least one antibiotic" is inconsistent with the Jepson format of claim 10 which recites " In an animal feed composition comprising crude protein and antibiotic supplement, the improvement comprising replacing all said antibiotic...". Claim 10 requires the improvement in the animal feed composition as replacing all of an antibiotic supplement. The recitation of "further comprising at least one antibiotic" in claim 14 lacks clarity and

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antecedent basis in view of the recited improvement of replacing all antibiotic supplements in claim 10. Appropriate clarification is needed.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-13, 18, 38 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Schroeder et al. US 4,169,041, July 3, 1979.

The claims are drawn to "in an animal feed composition comprising crude protein and an antibiotic supplement, the improvement comprising replacing all or a portion of said antibiotic supplement with an anti-bacterial amount of an anti-bacterial fatty acid component, wherein the anti-bacterial fatty acid component is a high lauric acid natural oil, having a high lauric acid content, wherein the high lauric acid oil is coconut or palm oil, wherein the lauric acid in the high lauric acid oil comprises 0.5% to 10% of the animal feed, wherein the animal feed composition is essentially free of antibiotic supplements, wherein the feed composition is feed for chickens, turkeys, lambs or veal calves produced for human consumption, wherein the combined amount of at least one anti-biotic and at least one anti-bacterial fatty acid component in the animal feed is sufficient to promote the health of the animal as compared to the feed composition without the added antibiotic and without the added anti-bacterial fatty acid component,

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wherein the combined amount of at least one anti-biotic and at least one anti-bacterial fatty acid component in the animal feed is sufficient to enhance the growth of the animal as compared to the feed composition without the added antibiotic and without the added anti-bacterial fatty acid component, wherein lauric acid in the high lauric acid oil comprises 2% to 10% of the animal feed and wherein the amount of said anti bacterial fatty acid component falls within the range of 2% to 7% by weight of said animal feed composition.

Schroeder et al teach a composition of an animal feed supplement (see comprising crude protein (e.g. blood, rabbit pellets, dried chicken manure etc, column 7 lines 21-39, table 4) and antibiotic (column 7 line 67) and high lauric acid natural oil such as coconut oil or palm oil (column 5 lines 50-54 and lines 60-62). Schroeder et al teach that high lauric acid natural oil is within 0% -30% or 5%-20% of the animal feed supplement (table 1 column 2). The instantly claimed range i.e. 2%-7% of the antibacterial fatty acid (i.e. high lauric acid natural oil complement falls within the 0%-30% or 5%-20% range of Schroeder et al. Therefore, the amount of coconut oil or palm oil (high lauric acid natural oil) in the composition of Schroeder et al is an anti-bacterial amount. Schroeder teaches that coconut oil and palm oil in said animal feed supplement is 5%-10% which is about 2.5% to 10% lauric acid content as the specification teaches that high lauric acid oils such as coconut oil or palm oil contain 50% lauric acid (specification p. 4 lines .4-6). The lauric acid content (2.5%to 10%) of the animal feed supplement of Schroeder et al anticipates the instantly claimed range of lauric acid content i.e. 0.5% to 10% and 2%-10%. Schroeder et al teach a particular

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embodiment of animal feed composition as set forth supra that is essentially free of antibiotic supplements (table 4 between columns 9 and 10). Said composition of Schroeder et al is an animal feed and feed is defined as food for animals especially livestock as evidenced by definition of feed (MSN Encarta online dictionary retrieved 6/12/2007). Livestock includes chickens kept on a farm as evidenced by Cambridge online dictionary retrieved 5/12/2007). Thus, the animal feed composition of Schroeder et al is for feed for chickens.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-14, 15-18, 25, 26, 38, 45 and 51 rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeder et al. US 4,169,041, July 3, 1979 in view of 21 CFR section 558.15 1997 (New animal drugs for use in animal feeds – antibiotic, nitrofurantoin)

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and sulfonamide drugs in the feed of animals) and J. Raloff, 1998, Science News vol. 154 p. 39).

The claims are drawn to "in an animal feed composition comprising crude protein and an antibiotic supplement, the improvement comprising replacing all or a portion of said antibiotic supplement with an anti-bacterial amount of an anti-bacterial fatty acid component, wherein the anti-bacterial fatty acid component is a high lauric acid natural oil, having a high lauric acid content (claim 10), further comprising at least one antibiotic, wherein the amount of antibiotic in the animal feed comprises less than 50% of an optimal antibiotic supplement (claim 14). The claims are also drawn to said composition of claim 10 which contains at least one antibiotic, wherein the amount of antibiotic in the animal feed comprises less than 50% of a maximal antibiotic supplement, wherein the amount of antibiotic in the animal feed comprises less than 50% of an optimal antibiotic supplement for controlling *Salmonella typhimurium*, wherein the amount of antibiotic in the animal feed comprises less than 50% of an allowable antibiotic supplement for controlling *Salmonella typhimurium*. The claims are also drawn to said composition according to claim 14 wherein the combined amount of at least one antibiotic and at least one anti-bacterial fatty acid is sufficient to promote health of the animal or enhance growth of the animal wherein the antibiotic is narasin/nicarbazin, chlortetracycline with salinomycin, monensin or Zn bacitracin.

Schroeder et al teach a composition of an animal feed supplement (see comprising crude protein (e.g. blood, rabbit pellets, dried chicken manure etc, column 7 lines 21-39, table 4) and antibiotic (column 7 line 67) and high lauric acid natural oil

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such as coconut oil or palm oil (column 5 lines 50-54 and lines 60-62). Schroeder et al teach that high lauric acid natural oil is within 0% -30% or 5%-20% of the animal feed supplement (table 1 column 2). The instantly claimed range i.e. 2%-7% of the antibacterial fatty acid (i.e. high lauric acid natural oil complement falls within the 0%-30% or 5%-20% range of Schroeder et al. Therefore, the amount of coconut oil or palm oil (high lauric acid natural oil) in the composition of Schroeder et al is an anti-bacterial amount. Schroeder teaches that coconut oil and palm oil in said animal feed supplement is 5%-10% which is about 2.5% to 10% lauric acid content as the specification teaches that high lauric acid oils such as coconut oil or palm oil contain 50% lauric acid (specification p. 4 lines .4-6). The lauric acid content (2.5%to 10%) of the animal feed supplement of Schroeder et al anticipates the instantly claimed range of lauric acid content i.e. 0.5% to 10% and 2%-10%. Schroeder et al teach a particular embodiment of animal feed composition as set forth supra that is essentially free of antibiotic supplements (table 4 between columns 9 and 10). Said composition of Schroeder et al is an animal feed and feed is defined as food for animals especially livestock (see definition of feed MSN Encarta online dictionary retrieved 6/12/2007). Livestock is includes chickens kept on a farm (see definition of livestock Cambridge online dictionary retrieved 5/12/2007). Thus, the animal feed composition of Schroeder et al is for feed for chickens.

The animal feed composition of Schroeder et al, free of antibiotic or including antibiotics (i.e. further comprising at least one antibiotic) as set forth supra does not disclose amounts of optimal antibiotic supplement (antibiotic supplement) or maximal

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antibiotic supplement or antibiotic supplement for controlling *S. typhimurium* or allowable antibiotic supplement for controlling *S. typhimurium* or antibiotics such as narasin/nicarbazin, chlortetracycline with salinomycin, monensin or Zn bacitracin.

21 CFR 558 teaches approved allowable animal feed antibiotics and their maximum amounts and optimal use levels in animal feeds (see print outs for section 4, 15, 78, 128 and 355). Section 128 teaches an allowable antibiotic i.e. chlortetracycline and the optimal amounts for controlling *Salmonella typhimurium*. 21 CFR 558 teaches the use of allowable antibiotics in animal feed for chickens, turkey and cattle.

J. Raloff teaches that "cases of antibiotic resistant human disease have clearly occurred due to bacteria from livestock treated with drugs" and teaches "propitious use of subtherapeutic antibiotics and if there are alternatives, consider using them".

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Schroeder et al to contain less than 50% of optimal antibiotic or less than 50% maximal antibiotic or optimal antibiotic for controlling *Salmonella typhimurium* or less than 50% allowable antibiotic for controlling *S. typhimurium* because 21 CFR 558 teaches federal approved allowable animal feed antibiotics and their maximum amounts and optimal use levels in animal feed. Using these federally mandated guidelines one of ordinary skill in the art can determine amounts less than 50% antibiotic to place in the composition of Schroeder et al. The motivation to modify the composition of Schroeder et al to contain less than 50% antibiotic is provided by Raloff et al who teach that cases of antibiotic resistant human disease have clearly occurred due to bacteria from livestock treated with drugs and

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teaches propitious use of subtherapeutic antibiotics and if there are alternatives, to consider using them. As the animal feed composition of the combination of Schroeder et al and 21 CFR 558 and Raloff et al is the same as the instant claims, then said composition is sufficient to promote the health of an animal and enhance the growth of the animal as compared to a feed composition without added antibiotic and without added anti-bacterial fatty acid.

Status of Claims

Claims 10-18, 25,26,38,45 and 51 are rejected. Claims 14,25,26 and 51 are objected to
No claims are allowed.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

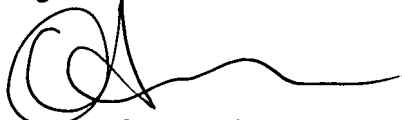
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can generally be reached on M-F 8:30 am - 5:00 pm. If

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attempts to reach the examiner by telephone are unsuccessful, the examiner's

Supervisor, Jeffrey Siew can be reached on 571-272-0787.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Oluwatosin Ogunbiyi

Examiner

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Patricia A. Duffy
PATRICIA A. DUFFY
PRIMARY EXAMINER